

EXHIBIT A

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Paper 31
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

DAIICHI SANKYO, INC. and
ASTRAZENECA PHARMACEUTICALS, LP,
Petitioner,

v.

SEAGEN INC.,
Patent Owner.

PGR2021-00030
Patent 10,808,039 B2

Before ERICA A. FRANKLIN, SHERIDAN K. SNEDDEN, and
CHRISTOPHER M. KAISER, *Administrative Patent Judges*.

SNEDDEN, *Administrative Patent Judge*.

DECISION
Granting Patent Owner's Request on Rehearing
37 C.F.R. § 42.71(d)
Denying Institution of Post-Grant Review
35 U.S.C. § 324

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I. INTRODUCTION

A. Status of the Proceeding

Daiichi Sankyo, Inc. and AstraZeneca Pharmaceuticals, LP (collectively, “Petitioner”) filed a Petition requesting a post-grant review of claims 1–5, 9, and 10 of U.S. Patent No. 10,808,039 B2 (Ex. 1001, “the ’039 patent”). Paper 1 (“Pet.”). Seagen Inc. (“Patent Owner”) filed a Preliminary Response to the Petition. Paper 7. Petitioner filed a Reply to Patent Owner’s Preliminary Response. Paper 8. Patent Owner filed a Sur-reply to Petitioner’s Reply. Paper 9.

We exercised our discretion to deny institution under 35 U.S.C. § 324(a) in view of the scheduled trial date of a parallel district court proceeding being nearly four months before our projected statutory deadline for issuing a final written decision, and other *Fintiv*¹ factors. Paper 11. Petitioner filed a request for rehearing. Paper 12. Concurrently therewith, Petitioner requested that the Board’s Precedential Opinion Panel (“POP”) reconsider the Denial Decision. Paper 13; Ex. 3001. The POP declined to review the issue raised in Petitioner’s POP Request. Paper 16. Upon consideration, we granted Petitioner’s Request for Rehearing and instituted post-grant review. Paper 17 (“Decision”).

Thereafter, Patent Owner filed a request for rehearing in light of the changed circumstances in the parallel district court proceeding and

¹ *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11 (PTAB Mar. 20, 2020) (precedential) (“*Fintiv* Order”).

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additionally in in the related proceeding PGR2021-00042. Paper 24 (“Reh’g Req.” or “Request”). Petitioner filed a Response (Paper 24, “Response”) and Patent Owner filed a Reply (Paper 26, “Reply”).

As discussed further below, in light of the changed circumstances in the parallel district court proceeding, we grant Patent Owner’s Request for Rehearing and exercise our discretion to deny institution. *See Sand Revolution II, LLC v. Cont’l Intermodal Grp. – Trucking LLC*, IPR2019-01393, Paper 24 at 8–9 (PTAB June 16, 2020) (informative) (considering changed circumstances (trial dates) after the original denial of institution as a basis to grant the rehearing request); *see also Canadian Solar Inc. v. The Solaria Corp.*, Case IPR2021-00095, Paper 17, 7 (Sept. 24, 2021) (“We do agree that the facts as they stand today do not support our Decision Denying Institution and, in light of the changed facts, we modify our earlier decision that exercised our discretion to deny institution.”).

II. DISCRETIONARY DENIAL OF INSTITUTION ON REHEARING

Institution of post-grant review is discretionary. *See* 35 U.S.C. § 324(a) (no mandate to institute review); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2140 (2016) (“[T]he agency’s decision to deny a petition is a matter committed to the Patent Office’s discretion.”). The Board’s precedential *NHK* decision explains that the Board may consider the advanced state of a related district court proceeding, among other considerations, as a “factor that weighs in favor of denying the Petition under § 314(a).” *NHK Spring Co. v. Intri-Plex Techs., Inc.*, IPR2018-00752,

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Paper 8 at 20 (PTAB Sept. 12, 2018) (precedential). The Board’s precedential *Fintiv* Order identifies several factors to be considered in analyzing whether the circumstances of a parallel district court proceeding warrant discretionary denial under *NHK*, with the goal of balancing efficiency, fairness, and patent quality. *Fintiv* Order 5–6. These factors are the following: 1) whether the court granted a stay or evidence exists that one may be granted if a proceeding is instituted; 2) proximity of the court’s trial date to the Board’s projected statutory deadline for a final written decision; 3) investment in the parallel proceeding by the court and parties; 4) overlap between issues raised in the petition and in the parallel proceeding; 5) whether the petitioner and the defendant in the parallel proceeding are the same party; and 6) other circumstances and considerations that impact the Board’s exercise of discretion, including the merits. *Id.* While *NHK* and the *Fintiv* Order pertain to discretionary denial of *inter partes* review under 35 U.S.C. § 314(a) and do not explicitly extend their application to post-grant review under § 324(a), we have applied the *NHK/Fintiv* framework in the context of post-grant review due to the similar statutory language and policy justifications associated with the exercise of discretion between §§ 314(a) and 324(a). *See* Denial Dec. 11–12.²

² *See also* Interim Procedure for Discretionary Denials in AIA Post-Grant Proceedings with Parallel District Court Litigation, available at: https://www.uspto.gov/sites/default/files/documents/interim_proc_discretionary_denials_aia_parallel_district_court_litigation_memo_20220621_.pdf (“Guidance Memo”). As noted therein, that guidance “applies to all proceedings pending before the Office.” *See* Guidance Memo at 9.

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In our Decision, we granted Petitioner's Request for Rehearing and instituted post-grant review in light of the fact that claims 6–8 of the '039 patent, challenged in PGR2021-00042, were dropped from the related district court litigation and further upon consideration that proceeding to trial before the Board in each of PGR2021-00030 and PGR2021-00042 would involve review of practically the same issues thereby raising concerns of inefficiency, duplicative efforts, and conflicting results if the Board were to institute trial in one proceeding, but not the other. Decision 6–7.

In its Rehearing Request, Patent Owner informs us that it has since disclaimed claims 6–8 of the '039 patent. Reh'g Req. 4 (citing Ex. 2041). Patent Owner additionally entered a request for adverse judgment in PGR2021-00042 citing its disclaimer under 35 U.S.C. § 253(a) and 37 C.F.R. § 1.321(a), disclaiming the entire patent term for claims 6–8 in the '039 patent from grant through expiration. PGR2021-00042, Paper 24.

Regarding claims 1–5, 9, and 10 challenged in this proceeding, Patent Owner informs us that

after a full trial on the merits of claim[s] 1–5, 9, and 10, a jury rejected Petitioner's enablement defense, as well as Petitioner's other invalidity defenses. The jury heard testimony from fact and expert witnesses for both parties, including Seagen's expert witness (Dr. Carolyn Bertozzi), from whom the Board has not yet heard. The jury found that Defendants had failed to prove that the asserted claims are invalid, and that Seagen had successfully proven Defendants infringed the asserted claims. Defendants' defenses of written description, enablement, and anticipation were the same as the grounds in the Petition. Thus, a jury has already determined that Petitioner's invalidity

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arguments, including its lack of enablement argument, lack merit.

Reh’g Req. 5.

In view of the above changed circumstances, Patent Owner contends the *Fintiv* factors strongly favor denial. *Id.* at 9.

Petitioner responds with its contention that there is not yet a final determination regarding invalidity by the district court and that “the equitable issue of prosecution laches remains pending in the district court.” Response 3. Petitioner also contends that numerous post-trial proceedings remain at the district court with respect to equitable issues and post-trial motions. *Id.* 3–4.

In considering the parties’ positions and the evidence of record, we note that we have been instructed not to exercise discretion to deny a petition when “the information presented at the institution stage presents a compelling unpatentability challenge.” Guidance Memo 4–5. We previously described “Petitioner’s argument that the claims lack enablement” as presenting “strong merits.” Paper 17, 3. Despite that determination, we believe the record as it stands currently does not “present[] a compelling unpatentability challenge” on the lack-of-enablement issue. Guidance Memo 4–5. The district court already has substantially completed its review of the enablement issue, and a jury has determined that the claims do not lack enablement. Given this new information, we cannot conclude that Petitioner’s enablement case is compelling.

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Having considered the parties' positions and evidence of record, summarized above, we agree with Patent Owner that a rehearing of our prior institution decision is appropriate due to the changed circumstances of: (1) the statutory disclaimer of claims 6–8 of the '039 patent, (2) Patent Owner's request for adverse judgment of related proceeding PGR2021-00042, and (3) the additional investment in the parallel proceeding by the district court and the parties, including the completion of a jury trial that resulted in a jury verdict not finding invalidity of the challenged claims. We further agree with Patent Owner that "[c]ontinuing with this proceeding would result in duplicative efforts and potentially conflicting results between the district court and the Board." Reh'g Req. 9. It is the combination of these changed circumstances, rather than any one of them individually, that compels the result we reach.

VI. CONCLUSION

In view of the above, we grant Patent Owner's Request. The Petition is denied, and no trial is instituted.

IV. ORDER

Accordingly, it is

ORDERED that Patent Owner's Request for Rehearing is *granted*;
and

FURTHER ORDERED that the Petition is *denied* as to all challenged claims, and no trial is instituted.

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